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- Published:**
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report:
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- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **GROUP B STREPTOCOCCUS VACCINE**

(57) Abstract: This application relates to improved Group B Streptococcus ("GBS") saccharide-based vaccines comprising combinations of GBS polysaccharides with polypeptide antigens, and *vice versa*, such that the polypeptide and the saccharide each contribute to the immunological response in a recipient. The combination is particularly advantageous where the saccharide and polypeptide are from different GBS serotypes. The combined antigens may be present as a simple combination where separate saccharide and polypeptide antigens are administered together, or they may be present as a conjugated combination, where the saccharide and polypeptide antigens are covalently linked to each other. Preferably, the immunogenic compositions of the invention comprise a GBS saccharide antigen and at least two GBS polypeptide antigens, wherein said GBS saccharide antigen comprises a saccharide selected from GBS serotype Ia, Ib, and III, and wherein said GBS polypeptide antigens comprise a combination of at least two polypeptide or fragments thereof selected from the antigen group consisting of GBS 80, GBS 91, GBS 104, GBS 147, GBS 173, GBS 276, GBS 305, GBS 313, GBS 322, GBS 328, GBS 330, GBS 338, GBS 358, GBS 361, GBS 404, GBS 656, GBS 690, and GBS 691.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/29167

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 39/385, 39/02, 39/09, 39/00

US CL : 424/197.11, 234.1, 244.1, 184.1, 236.1, 831

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/197.11, 234.1, 244.1, 184.1, 236.1, 831

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02/34771 A2 (CHIRON S.P.A.) 02 May 2002 (02.05.2002), pages 7, 841 and 842.	1-17
Y	US 6,372,222 B1 (MICHON et al) 16 April 2002 (16.04.2002), claims and Examples.	1-17
Y	US 6,426,074 B1 (MICHEL et al.) 30 July 2002 (30.06.2002), Example 14.	1-17



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

15 April 2004 (15.04.2004)

Date of mailing of the international search report **02 AUG 2004**

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/29167

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

GBS saccharide antigen species: serotype Ia; serotype Ib; and serotype III.

The claims are deemed to correspond to the species listed above in the following manner:
Claims 1 and 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The saccharide antigen species listed above do not share significant structural elements and immunogenic specificity.

Continuation of B. FIELDS SEARCHED Item 3:

DIALOG, WEST, EMBASE, BIOSIS, MEDLINE

GBS or group B streptococc?, (Ia or Ib or III), GBS79, GBS80 to GBS 691, inventor's name